



**One Hundred Ninth Congress
U.S. House of Representatives
Committee on Homeland Security
Washington, DC 20515**

May 9, 2005

The Honorable Michael Chertoff
Secretary
U.S. Department of Homeland Security
Washington, DC 20528

Dear Secretary Chertoff:

I am concerned about the policies leading to a low level of anthrax vaccine available for use in the Strategic National Stockpile (SNS), and would like more information about the Department of Homeland Security's underlying role in this decision-making as the Co-Chair of the Weapons of Mass Destruction Medical Countermeasures Subcommittee.

Public reports have indicated that the number of anthrax vaccine doses currently in the SNS stands at between zero and 500—a number that falls far short of being able to cover the threat to the American civilian population—because a new type of anthrax vaccine under development as part of Project BioShield has not yet completed the development and approval process. Indeed, it has been reported that not a single anthrax vaccine dose has been added to the SNS since September 11, 2001.

A contract was just announced on May 6, 2005 to deliver approximately 5 million doses of an older version of the anthrax vaccine that is already successfully developed, but it is unclear when this delivery will be made or why this number of doses was all that was requested. Additionally, a memorandum of understanding (MOU) with the Department of Defense permits use of its stockpile of anthrax vaccine in the event of a domestic national emergency, but it is unclear how this arrangement would work if the military required the vaccine for its own use.

The new type of anthrax vaccine under development in Project BioShield has some unique benefits, but is offered by only one manufacturer and is not yet approved by the Food and Drug Administration (FDA). I know that Project BioShield's purpose is to develop vaccines from an experimental stage, and I support efforts to develop new anthrax vaccines such as those offered by this unique technology. However, I am

concerned about the possibility that if this new technology is not ultimately successful, or does not receive FDA approval, the SNS may be left without an adequate supply of anthrax vaccine in the case of an emergency. Even if a waiver of FDA approval was given due to a national emergency, it is unclear how quickly this new vaccine could be manufactured.

I am especially concerned about potential delays because I know that the draft National Performance Goal (NPG) relies on mobilizing vaccine doses in the SNS as part of the National Planning Scenario (NPS) for a bioterrorist attack. If the likelihood that the SNS will have anthrax vaccines in the case of a bioterrorist attack is too low, then both the NPS and the NPG could be flawed. If that is the case, then first responders all across the nation are relying on a strategy for combating a bioterrorist attack that exists only on paper.

I would appreciate you advising me on the following:

1. What role did the Department have in the decision to award the Project BioShield contract for new anthrax vaccine development?
2. What position did the Department have on the Project BioShield contract?
3. Did the Department have any role in reviewing the contract to purchase the new type of anthrax vaccine for the SNS?
4. What position did the Department take on the SNS contract for the purchase of the new type of anthrax vaccine?
5. What position did the Department take on the decision to order 5 million doses of the older type of anthrax vaccine for the SNS, and why did it take so long before the need for these doses was recognized?
6. Has the Department factored into the NPG the possibility that the new type of anthrax vaccine contracted for development under Project BioShield and to be purchased by the SNS might never be successfully developed?
7. What impact would the failure to have an adequate amount of usable anthrax vaccine in the SNS have on the usefulness of the NPG?
8. What impact would a failure to have an adequate amount of usable anthrax vaccine in the SNS have on the Department's other plans for protecting the nation in the event of a bioterror attack?

I would appreciate a timely response to my inquiries no later than June 1, 2005.

Sincerely,

A handwritten signature in black ink that reads "Bennie G. Thompson". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Bennie G. Thompson
Ranking Member
House Committee on Homeland Security